

WASHINGTON LEGAL FOUNDATION

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July 19, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Advanced Notice of Proposed Rule on the Labeling of Foods Treated with Ionizing Radiation, Docket No. 98-N-1038, 64 Fed. Reg. 7834 (February 17, 1999)

Dear Docket Clerk:

The Washington Legal Foundation (WLF) hereby submits these comments in support of eliminating all labeling requirements for foods treated with ionizing radiation.

Interests of the Washington Legal Foundation

WLF is a nonprofit public interest law and policy center with supporters in all 50 states. While WLF engages in litigation and administrative proceedings in a variety of areas, WLF devotes a substantial portion of its resources to promoting the interests of a free-market economy and to defending the rights of individuals and businesses to go about their affairs without excessive influence from government regulators. In particular, WLF petitioned FDA in 1993 and in 1998 to lift its overly-severe restrictions on the dissemination of information regarding off-label uses of FDA-approved products, and in 1995 petitioned FDA to ease its restrictions on direct-to-consumer prescription drug advertisements. Among WLF members are individuals who seek to eliminate the current labeling requirements for foods treated with ionizing radiation.

The current labeling requirement causes undue consumer confusion and anxiety

In 1986, the Food and Drug Administration (FDA) approved the use of ionizing radiation, concluding that irradiation is safe, and does not affect the nutritional value of foods. In addition, the agency concluded that irradiation provides several benefits such as disinfecting the food of pests and microorganisms, and slowing down food spoilage. 51 Fed. Reg. 13376 (1986). When it issued the final rule, the FDA also issued a requirement that manufacturers include the statement, "Treated with radiation (or irradiation)" on the wholesale label, and on the retail label, along with the radura or radiation logo for a short period of two years. This requirement was

originally intended to familiarize consumers with the process of irradiation, not to serve as a warning. The two-year period was extended in 1988 and the labeling requirement was made permanent in 1990.

The FDA's permanent labeling requirement contradicts the agency's own approval of food irradiation because the statement and logo are perceived as a consumer warning. This required radiation statement and logo are confusing and misleading to consumers. In fact, the FDA itself has acknowledged that many consumers may perceive the radiation disclosure as a warning, caution, or health hazard. 51 Fed. Reg. 13376, 13388 (1986). Because consumers are less likely to buy food items with radiation statements or logos, the labeling requirement actually discourages manufacturers from using irradiation, a process proven to reduce the dangers of harmful pathogens in food.

The FDA has sought to overcome the consumer misunderstandings about irradiation of foods by suggesting a public education campaign. However, the FDA has refused to participate in any education programs, and has refused to encourage participation by any other federal agency that has a role in public education about diet and health. Since the regulation was implemented in 1986, the public perception about irradiated food has not changed. Many companies refuse to use irradiated products because of the public's controversial attitude. This misunderstanding is largely due to the required disclosure statement, "Treated with radiation (or irradiation)" and the radura logo. The statement does not serve its purpose as a consumer education effort; rather it gives the public the wrong idea and acts more like a caution or a warning.

Commercial free speech rights harmed

The government cannot compel companies to reveal information about their products based on consumer curiosity. Courts have ruled that consumer interest cannot justify a law requiring "manufacturers to publish the functional equivalent of a warning" when the method of treatment has no bearing on the safety of a product. IDFA v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996). Instead, consumers can exercise their option to purchase products from manufacturers who voluntarily disclose information about the treatment and handling of their products. Id.

The radiation statement and logo are the functional equivalent of a warning. Irradiation is recognized by the FDA as having no adverse health effects. Therefore, it is inappropriate to require a radiation warning. The requirement infringes on companies' rights to use irradiation without being forced to simultaneously discourage consumption and purchase by consumers.

The FDA does not require dispositive labeling of other similar types of treated food

The FDA has made decisions *not* to require dispositive labeling on genetically engineered foods, dairy products from cows treated with rBST, and foods containing environmental

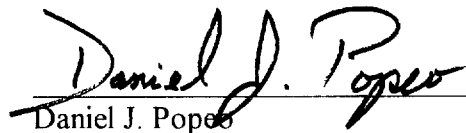
contaminants or residues of pre-harvest chemicals. WLF is aware, however, of a recent lawsuit, International Center for Technology Assessment v. FDA, which seeks to require labeling on genetically modified food. The FDA has countered consumer groups' contentions that they have a "right to know" about these aspects of food handling with the argument that the labeling information did not relate to the safety of the food and that such labeling could result in consumer confusion and apprehensions about the safety of the foods.

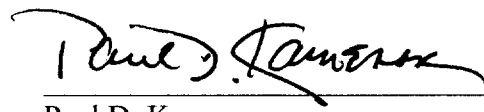
Conclusion


When the FDA implemented its rule regarding labeling of irradiated foods in 1986, it argued that irradiated foods are not unprocessed foods. Therefore, the lack of a radiation statement and logo would be an implied misrepresentation to the public that the food was unprocessed. However, when a food does carry a radiation label, the false representation is even stronger because it implies that there is cause for warning or that the consumer will be bearing a risk by consuming that particular food, when in fact, the irradiation treatment technology can actually increase the safety of the food supply. If the FDA refuses to eliminate the labeling requirement, the agency should consider requiring a statement that more accurately portrays to the public that the process of irradiation is safe and beneficial. Some less threatening terms include "cold pasteurization" or "electronic pasteurization." However, the current required statement is inappropriate and should no longer be required. The complete elimination of any labeling requirement would put a stop to baseless consumer anxieties and such a policy would be more consistent with the FDA's labeling policies of other types of food treatments.

Additionally, the courts have been clear that the FDA may not force manufacturers to publish warnings or their equivalents when food treatments are proven to be safe. As long as the current labeling requirement remains in place, manufacturers will be forced to prolong the consumer misunderstandings about food irradiation or stop using the process of food irradiation, a safe and beneficial food treatment.

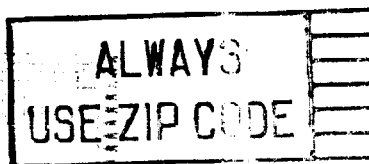
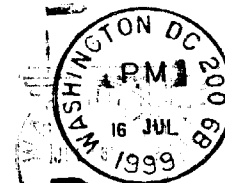
Respectfully submitted,


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